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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,879	06/21/2001	Avi J. Ashkenazi	P1110P1C1	9003

9157 7590 02/28/2007

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
KAUFMAN, CLAIRE M	
ART UNIT	PAPER NUMBER
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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KAUFMAN, CLAIRE M	
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DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,879	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-34 and 55-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29-34 and 63-66* is/are allowed.

6)☒ Claim(s) *55-62,67-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Prosecution is reopened and the suspension and indication of allowability is withdrawn in view of the new rejections set forth below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 55-62 and 67-68 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55-61, 64-75, 78-81 of copending Application No. 10/242,383. Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibody of the instant application would bind the same Apo-2DcR polypeptide comprising SEQ ID NO:1 as the antibody of the copending application. Likewise the antibody which is a monoclonal, chimeric or blocking antibody is also not patentably distinct (see claims 56, 60 and 61, respectively, of copending application).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been

obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 55-62 and 67-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Patent 6,261,801 (Wei et al.).

US Patent 6,261,801 teaches "TRID" or "tumor necrosis factor receptor 5" ("TNFR-5") with the amino acid sequence of SEQ ID NO:2, which has the same sequence as the sequence of SEQ ID NO:1 of the instant application. Also taught are antibodies that bind TRID, including monoclonal and chimeric antibodies, including humanized antibodies(col. 22, lines 37-65, and col. 23, lines 24-35, respectively), and antigenic index indicating epitope-bearing regions of the protein which are contained within the extracellular domain (Fig. 3) to which antibodies are made (*e.g.*, col. 20, lines 61-65). Antagonist, including blocking antibodies, antibody raised against TRID are also set forth (col. 29, lines 15-31). Well known methods of producing such antibodies are taught (col. 22, lines 26- col. 23, line 35).

This rejection has been reintroduced even though it was initially withdrawn in the Office action mailed 06/03/03 in view of Applicant's arguments. The reasons it is now being applied is that the Examiner has become aware of the basis for an enabling disclosure in the priority documents to which US 6,261,801 claims priority, therefore providing the patent with an effective filing date earlier than the instant application's. That is, in the patent's earliest priority application, 60/035,496, it was established that soluble forms of TNFR-5 receptor (renamed TRID in later filed application 60/054,885) can function as antagonists, and antagonists are capable of inhibiting apoptosis (p. 51, lines 24-29 and p. 54, lines 28-30). Additionally disclosed is the administration of an antagonist to reduce selective killing of CD4 T-lymphocytes in HIV+ individuals (p. 55, line 27- p. 56, line 17). The latter antagonist role is supported by art (*e.g.*, Miura et al., J. Exp. Med. 193(5):651-9, 2001).

Note that US Patent 6,261,801 does not teach an antibody to TRID that also binds other Apo-2 ligand antibodies. In view of the low sequence identity shared by Apo-2DcR and the other Apo-2 ligand receptors recited in claim 63, one could not have readily envisioned an antibody that had the required shared binding properties set forth in the claim. This is supported by the findings in US 6,252,050, which is commonly owned and has a later effective filing date than the instant application, showing in TABLE 1 (col. 30) that immunization with either DR4 or Apo-2 alone did not produce cross-reactive antibodies.

Prior Art

It is also noted that while provisional priority application 60/049,911 discloses the complete Apo-2DcR protein and encoding nucleic acid, it does not disclose a specific antibody; however, the prior art of record does not teach an anti-Apo-2DcR antibody as claimed. This includes the lack of teaching of an antibody to DR4 (TRAIL-1), Apo-2 (DR5, TRAIL-2) or DcR2 (TRAIL-4), which is pertinent since disclosed antibodies 6D10.97 and IC5.24.1 bind these receptors as well as Apo-2DcR, albeit with generally lower affinity (Fig. 16).

Term Usage

It is noted that the art also refers to Apo-2DcR as TR5, TNFR-5, TRID, LIT, TRAIL-R3 and DcR1.

Conclusion

Claims 29-34 and 63-66 remain allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (571) 272-0829.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax; the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire M. Kaufman, Ph.D.
Patent Examiner, Art Unit 1646
December 20, 2005

LORRAINE SPECTOR
PRIMARY EXAMINER